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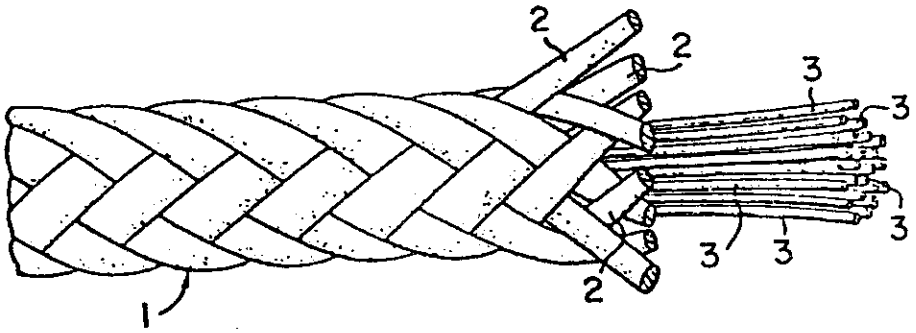
Could you provide
a translation of summary please

Subject: GERMAN PATENT APPLICATION 29 49 920 AND "MATSUDA MEDICAL"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers (2) surrounding fine platinum fibers or pure gold fibers (3) swaged to at least one surgical needle (4).

2. A surgical suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.



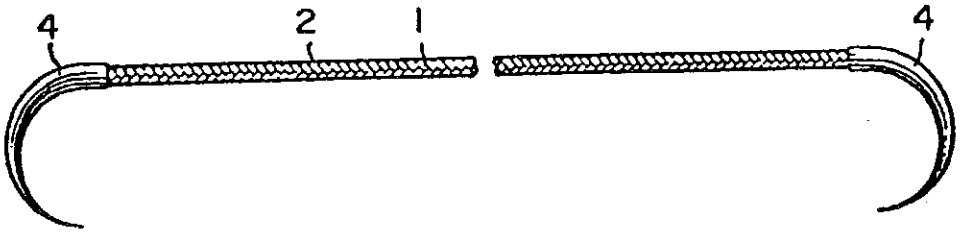


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FIG. 1

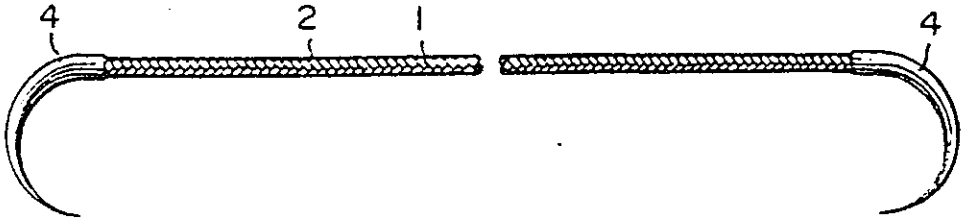


FIG. 2

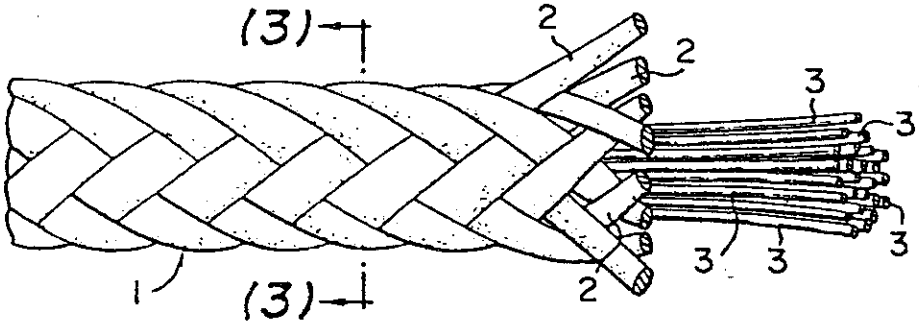
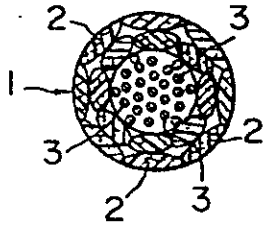


FIG. 3



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Chirurgisches Nahtmaterial

P A T E N T A N S P R Ü C H E

1. Chirurgisches Nahtmaterial, g e k e n n z e i c h n e t durch ein rohrförmiges Geflecht (1) aus sehr dünnen zusammengeflochtenen chemischen Faserfäden (2), durch eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden (3), die in das rohrförmige Geflecht (1) über dessen gesamte Länge eingesetzt sind, und durch wenigstens eine chirurgische Nadel (4), die in einem Stück mit einem Ende des rohrförmigen Geflechts (1) verbunden ist.

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2. Chirurgisches Nahtmaterial nach Anspruch 1, dadurch g e k e n n z e i c h n e t , dass die sehr dünnen chemischen Faserfäden (2), die das rohrförmige Geflecht (1) bilden, Polytetrafluoräthylen-Faserfäden sind.

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Beschreibung

Die Erfindung betrifft ein chirurgisches Nahtmaterial.

Als Nahtmaterialien für chirurgische Eingriffe werden bisher in üblicher Weise Materialien aus tierischen Fasern, beispielsweise aus Seide, verwandt. Diese Nahtmaterialien aus tierischen Fasern rufen jedoch eine Reibung mit den inneren Organen bei Bauchoperationen hervor und bringen die Gefahr mit sich, dass die verschiedenen Funktionen der Organe beeinträchtigt werden, was manchmal zu einer Abstossung führt.

Nach der Operation kann darüberhinaus das Nahtmaterial selbst einen Kapillareffekt bewirken. Wenn weiterhin ein künstliches Organ und ein natürliches Organ verbunden werden, besteht die Gefahr, dass das Nahtmaterial selbst mit dem natürlichen Organ verwächst und dessen normale Funktion behindert. Wenn weiterhin eine Infektion auftritt, ist es bisher mit dem Nahtmaterial aus tierischen Fasern unmöglich, die Organfunktion wieder herzustellen, bis das Nahtmaterial entfernt oder körperlich abgestossen ist.

Mit Nahtmaterialien aus Seide oder einem ähnlichen Material war es weiterhin bisher unmöglich, röntgenologisch die miteinander vernähten Teile nach der Operation zu beobachten, so dass es schwierig war, die Funktion des Organs des Körpers nach der Operation zu verfolgen und zu analysieren.

Aufgabe der Erfindung ist daher die Entwicklung eines chirurgischen Nahtmaterials, das die oben beschriebenen Nachteile der bekannten Nahtmaterialien nicht aufweist, d.h. das kein Blut oder andere Körperfluide, Bakterien

usw. überträgt und sgomit keinen Kapillareffekt zeigt, und das ohne jede beesondere Behandlung bei einer chirurgischen Operattion einsatzbereit ist.

Diese Aufgabe wird eerfindungsgemäss durch ein chirurgisches Nahtmaterial ggelöst, das ein rohrförmiges Geflecht aus sehr dünnen zusammengeflochtenen chemischen Faserfäden, eine Anzahl vvon sehr dünnen Platinfäden oder reinen Goldfäden, die iin das rohrförmige Geflecht über dessen gesamte Länge eingessetzt sind,und wenigstens eine chirurgische Nadel aufweisst, die in einem Stück mit einem Ende des rohrförmigen Geflechts verbunden ist.

Ein besonders bevorzugtes Ausführungsbeispiel des erfindungsgemässen chirurgischen Nahtmaterials zeichnet sich dadurch aus, daass die miteinander vernähten Teile des Körpers nach derr Operation röntgenologisch beobachtet werden können, so daass die Funktion des Organs des Körpers nach der Operation verfolgt und analysiert werden kann.

Im folgenden wird aanhand der zugehörigen Zeichnung ein bevorzugtes Ausführungsbeispiel der Erfindung näher erläutert:

Fig. 1 zeigt eine teilweise weggebrochene Seitenansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaterials.

Fig. 2 zeigt eine vergrösserte Teilvorderansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaaterials, wobei die inneren Metallfäden teilweise durch Abschneiden und Weglassen des äusseren Geflechtes freigelegt sind.

Fig. 3 zeigt eine Schnittansicht längs der Linie 3-3 in Fig. 2.

Wie es in der Zeichnung dargestellt ist, weist das Ausführungsbeispiel des erfindungsgemässen Nahtmaterials ein rohrförmiges Geflecht 1 auf, das aus sehr dünnen zusammengeflochtenen chemischen Faserfäden 2 besteht. Eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden 3 ist in das rohrförmige Geflecht 1 über dessen gesamte Länge eingesetzt. Eine chirurgische Nadel 4 ist in einem Stück mit beiden Enden jeweils oder mit einem Ende des rohrförmigen Geflechtes 1 verbunden, das die Platinfäden oder die reinen Goldfäden 3 umschliesst, die in das Geflecht 1 eingesetzt sind.

Als Faserfäden 2, die das rohrförmige Geflecht 1 bilden, können solche Faserfäden, die eine glatte Oberfläche und eine hohe Dauerhaftigkeit, Abbriebfestigkeit, Biegefestigkeit und Zugfestigkeit haben, beispielsweise Polyfluoräthylen-Faserfäden oder Polyester-Faserfäden, verwandt werden.

Das rohrförmige Geflecht 1 ist dadurch gebildet, dass eine Anzahl von Faserfäden 2 mit einer längenbezogenen Masse von $1/9 \cdot 10^2$ tex zusammengeflochten sind, wobei bei dem in den Fig. 2 und 3 dargestellten Ausführungsbeispiel 16 Fäden verwandt sind.

Die sehr dünnen Platinfäden oder die sehr dünnen reinen Goldfäden 3, die in das rohrförmige Geflecht 1 eingesetzt sind, haben eine Stärke von etwa 50 µm im Durchmesser, wobei etwa 20 derartige Fäden verwandt werden. Diese Platinfäden oder diese reinen Goldfäden 3 haben keinen Einfluss auf die

inneren Organe, wenn sie sich im Körper befinden.

Die chirurgische Nadel 4 besteht aus rostfreiem Stahl oder einem Spezialstahl.

Mit Hilfe des oben beschriebenen Nahtmaterials kann das Ausführen der Naht reibungslos erfolgen, ohne die inneren Organe unnötigerweise zu verletzen, da die Fäden 2, aus denen das Geflecht 1 besteht, glatte Oberflächen haben. Aufgrund der Art seines Materials überträgt das Nahtmaterial darüberhinaus kein Blut oder andere Körperfluide aufgrund des Kapillareffektes. Ohne jede besondere Behandlung des Nahtmaterials können daher ein Anhaften und Fortpflanzen von Bakterien verhindert werden und können selbst dann, wenn Bakterien übertragen werden, die infizierten Bereiche leicht ausgeheilt werden.

Nach dem chirurgischen Eingriff können weiterhin röntgenologische Beobachtungen der Gewebebildung des lebenden Körpers und der Ergebnisse einer Langzeitgewebebildung nach der postoperativen Behandlung, beispielsweise der Nahtbildung, erfolgen und ist es gleichfalls möglich, fortlaufend Änderungen im Zustand des Operationsbereiches mit dessen Wanderung und andere bisher unbekannte Funktionen der Organe des Körpers auf Röntgenfilmen zu beobachten, was für die medizinische Behandlung ausserordentlich nützlich ist.

Das erfindungsgemässe chirurgische Nahtmaterial ist somit am besten für den chirurgischen Einsatz künstlicher Organe geeignet.

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FIG. 1

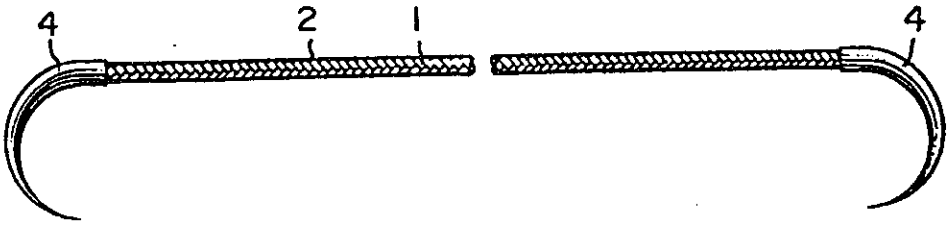


FIG. 2

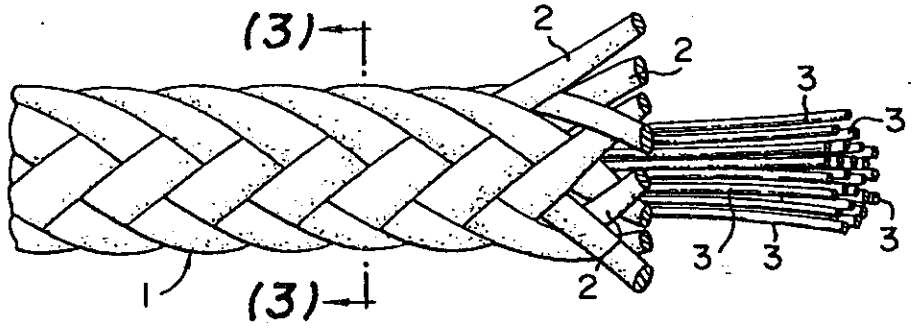
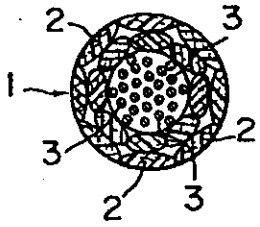


FIG. 3



ALLEN TRANSLATION SERVICE

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Subject: German Patent Application 29 49 920 and "Matsuda Medical"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers or pure gold fibers (3) swaged to at least one surgiccal needle (4).
2. A surgica suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.

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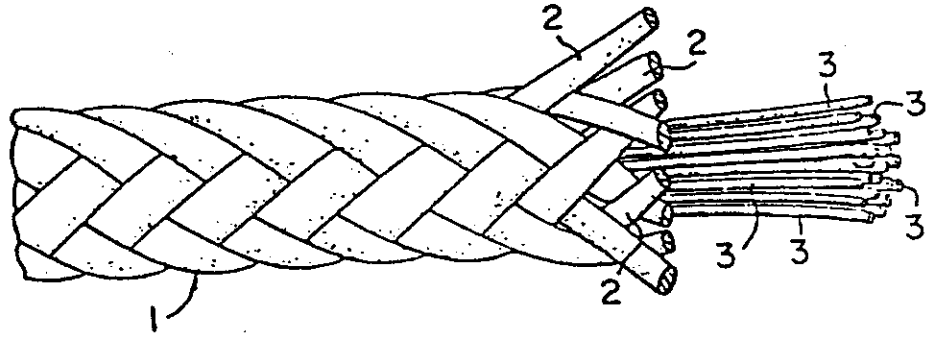
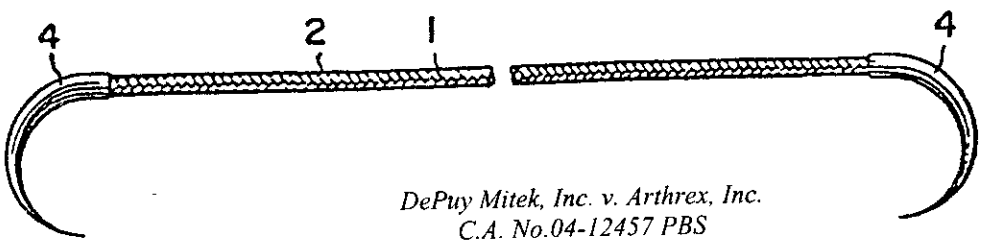
SURGICAL SUTURE MATERIAL

PATENT CLAIMS

1. Surgical suture material characterized by a tubular braid (1) made of very thin synthetic fibers braided together (2), by a number of very thin platinum fibers or pure gold fibers (3) that are inserted into the tubular braid (1) over its entire length, and by at least one surgical needle (4) which is joined integrally to one end of the tubular braid (1).

2. Surgical suture material according to Claim 1, characterized by the fact that the very thin synthetic fibers (2) that form the tubular braid (1) are polytetrafluoroethylene fibers.





Description

The invention relates to a surgical suture material.

Up to now, materials made from animal fibers, for example silk, have commonly been used as suture materials for surgical operations. These suture materials made of animal fibers, however, cause friction with the internal organs during abdominal operations and are accompanied by a danger that the various functions of the organs will be impaired, which sometimes leads to rejection.

In addition, after the operation, the suture material itself can have a capillary effect. Further, when an artificial organ and a natural organ are joined there is a danger that the suture material itself will be overgrown by the natural organ and hinder its normal functioning. Moreover, when an infection occurs, it has up to now been impossible with animal fiber sutures to restore the organ function until the suture material is removed or physically rejected.

Further, with suture materials made of silk or a similar material, radiological observation of the parts sutured together has been impossible after the operation, so that it has been difficult to observe and analyse the functioning of the body organ after the operation.

The objective of the invention is therefore the development of a surgical suture material that does not have the above-described disadvantages of common suture materials, that is, which does not transport any blood or other body fluids, bacteria, etc., and thus does not display any capillary effect, and that is ready for use in a surgical operation without any special treatment.

This objective is achieved according to the invention by a surgical suture material that has a tubular braid made of very thin synthetic fibers braided together, a number of very thin platinum fibers or pure gold fibers which are inserted into the tubular braid over its entire length, and at least one surgical needle that is joined integrally to one end of the tubular braid.

A particularly preferred example of a realization of the surgical suture material of the invention is characterized by the fact that the parts of the body sutured together can be observed radiologically after the operation, so that the functioning of the body organ can be observed and analysed after the operation.

A preferred realization of the invention is described in more detail below with the aid of the accompanying drawings:

Fig. 1 shows a partially cut away lateral view of the realization of the suture material of the invention..

Fig. 2 shows a magnified partial frontal view of the realization of the suture material of the invention, with the inner metal filaments partially exposed by cutting away or omitting the outer braid.

Fig. 3 shows a sectional view along the line 3-3 in Fig. 2.

As is shown in the drawing, the exemplary realization of the suture material of the invention shows a tubular braid 1, which is composed of very thin synthetic fibers braided together. A number of very thin platinum fibers or pure gold fibers 3 are inserted into the tubular braid 1 over its entire length. A surgical needle 4 is joined integrally with both ends or with one end of the tubular braid 1 which surrounds the platinum fibers or the pure gold fibers that are inserted into the braid 1.

As for fibers 2 that form the tubular braid 1, those fibers can be used that have a smooth surface and a high durability, resistance to abrasion, bending strength and tensile strength, for example, polyfluoroethylene fibers or polyester fibers.

The tubular braid 1 is formed by braiding together a number of fibers 2 with a lengthwise mass of $1/9 \times 10^2$ tex, with 16 fibers being used in the exemplary realization shown in Figs 2 and 3.

The very thin platinum fibers or the very thin pure gold fibers 3 that are inserted into the tubular braid 1 have a diameter of about 50 um, with about 20 fibers of this kind being used. These platinum fibers or these pure gold fibers have no effect on the internal organs when they are in the body.

The surgical needle 4 is composed of stainless steel or a special steel.

By means of the above described suture material, the realization of suturing can take place smoothly without injuring the internal organs unnecessarily, since the fibers 2 of which the braid 1 is composed have smooth surfaces. Furthermore, because of the type of material of which it is composed, the suture material does not transport any blood or other body fluid by capillary action. Adhesion and transmission of bacteria can therefore be hindered without any special treatment of the suture material and even when bacteria are transferred the infected region can be healed easily.

Further, after the surgery, it is possible to make radiological observations of tissue formation in the living body and of the result of long-term tissue formation after the post-operative treatment, for example the formation of an anastomosis, and it is likewise possible to observe on x-ray film progressive changes in the state of the area operated on with its migration and other heretofore unknown functions of the body organs, which is extremely useful for the medical treatment.

The surgical suture material of the invention is thus best suited for the surgical implantation of artificial organs.

PCT

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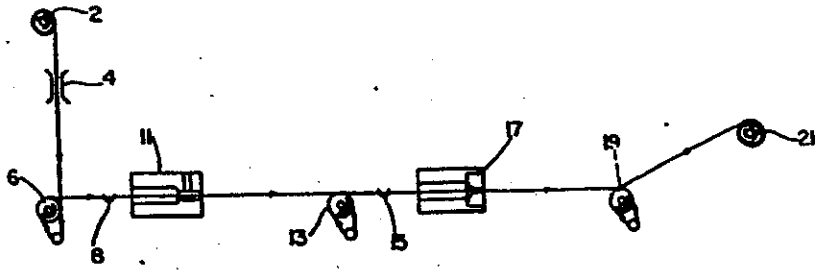
(54) Title: COMPOSITE SURGICAL SUTURES



(57) Abstract

A composite surgical suture of extraordinary high knot strength and capable of use over a range of United States Pharmacopeia (USP) suture sizes is prepared by coating or covering a core of a fiber-forming synthetic polymer material having a knot tenacity of at least 7 grams per denier with a conventional suture material. Illustrative of suitable core materials are Kevlar and high strength fully chain-extended crystalline polyethylene.

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COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to improved surgical sutures having extremely high knot strength and to methods for their preparation. More particularly, the invention is directed to composite surgical sutures having a knot strength that enables them to be used over a range of suture sizes classified by the United States Pharmacopeia (USP).

Brief Description of the Prior Art

Surgical sutures are generally divided into two broad classes: (1) absorbable sutures, either natural or synthetic, which are absorbed by the body and (2) non-absorbable sutures, which remain in the body for prolonged periods of time or are removed when the wound heals.

From the patient's viewpoint, whether an absorbable or non-absorbable suture is employed, assuming no toxicity of the suture implant, it is a surgical dictum that the finest suture should be used and that the knot should have the least mass. This dictum is based upon the belief that problems in suture implants are directly related to the size of the suture and the bulk of the mass, i.e., the larger the bulk, the greater the probability of trouble in healing.

Undoubtedly, this was the rational for the original establisnment of the USP classification which divides non-absorbable sutures into seventeen sizes: 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7. A few additional

sizes are used which are not USP. Considering that silk was the most widely used non-absorbable suture in the mid-twenties and thirties, this size differentiation was based upon manufacturing. These seventeen sizes could be differentiated one from another by eye. If a finer differentiation were desired, it would not be accomplished becasue of the variation in the raw material as extruded by the silk worm. This classification has been quite useful. Obviously, the number of sizes cannot be considered "standardization" by any means. The sizes are numerous. Unfortunately, it has not been possible to coalesce size because the finer sizes do not have the adequate knot break strength to substitute for the next size.

A further long term problem in surgery is post-operative hernia. It is a truism that scar tissue never achieves the tensile strength of normal tissue. Hernias have occurred many years post-operably through the scar. If a suture were developed which would leave as a residue a non-absorbable suture to support that scar tissue, it would undoubtedly decrease and most likely eliminate the post-operative hernia as a complication.

Composite sutures having a reinforcing core are known in the prior art. None, however, achieve the aforementioned characteristics desired in a suture.

Accordingly, it is an object of the invention to provide a surgical suture with knot strengths so great that suture of much less foreign material is left in the body.

Another object of the invention is to provide a surgical suture having a knot strength that renders it useful over a range of surgical sizes within the USP classification of graded suture sizes, and thus

having the ability to replace the USP graded scale of sizes with just a few finer sutures whose strength would cover the entire range.

A further object of the invention is to provide a composite suture which leaves a residue of non-absorbable suture to support scar tissue and, therefore, decreases or eliminates post-operative hernia as a complication.

Another object of the invention is to provide a method of preparing surgical sutures having extremely high knot strength whose surface characteristics can be tailored to meet desired properties.

A further object of the invention is to provide composite sutures capable of using needles which more closely approximate the outer diameter of the suture.

A further object of the invention is to provide a composite suture having lateral strength, that is, a suture stabilized against abrasion, kinking and/or fibrillation during knotting.

SUMMARY OF THE INVENTION

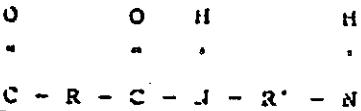
These and other objects of the invention are obtained by a sterile, surgical suture having an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier coated with a film and fiber-forming surgical material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

The elongated core of the sutures of the invention can be formed of any fiber-forming synthetic polymer, such as a polyamide, polyolefin, polyester

and the like, having a straight pull tenacity of at least 15 grams/denier, preferably up to 70 or more grams/denier and a knot tenacity of at least 7 grams/denier, preferably up to 30 or more grams/denier. By "knot tenacity" as used herein and in the appended claims is meant knot break strength divided by the denier. Unless the synthetic polymer making up the suture core of the invention meets the aforementioned knot tenacity properties, the resulting coated core fails to provide a suture which achieves the desired objects of the invention.

Illustrative of synthetic polymer materials suitable for use as the core of the suture of the invention are fiber-forming aromatic polyamides in which the chain extending bonds from each aromatic nucleus are essentially coaxial or parallel and oppositely directed. The term "aromatic nucleus" is used herein to include individual enchained aromatic rings and fused-ring aromatic divalent radicals. The preferred polymers include carbocyclic aromatic polyamides containing up to 2 aromatic rings, including enchained non-fused rings (e.g. 4, 4'-biphenylene) or fused rings (e.g. 1, 5-naphthalene) per amide linkage. The chain-extending bonds from these aromatic rings are para-oriented and/or essentially coaxial or parallel and oppositely directed.

Highly preferred polyamides are characterized by recurring units of the formula:

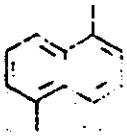
(I) 

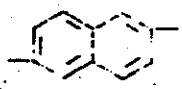
wherein R and R' (when the chain extending bonds are essentially coaxial) are selected from the group of:

 1,4-phenylene, and

 4,4'-biphenylene

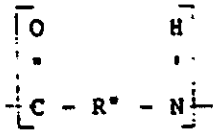
and R and R' (when the chain extending bonds are essentially parallel) are selected from the group of:

 1,5-naphthylene, and

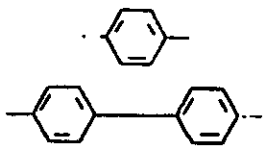
 2, 6-naphthylene

R and R' may be the same or different and may contain substituents on the aromatic nuclei.

Additional highly preferred polyamides of this invention are characterized by recurring units of the formula:

(II) 

wherein R" is selected from the group of:



Similarly R" may contain substituents on the aromatic nuclei.

As previously stated, the aromatic nuclei of the polymers of this invention may bear substituents. These substituents should be non-reactive during the polymerization and preferably also should be non-reactive (e.g. thermally) during subsequent processing of the polymer, e.g., heat treating of a shaped fiber thereof. Such reactivity is undesirable in that it may cause cross-

linking of the polymer and may adversely effect the dope and/or fiber properties. Among the preferred non-reactive substituents may be names halogens (e.g., methoxy and ethoxy), cyano, acetyl, and nitro. Other suitable substituents non-reactive during the polymerization will be evident to those skilled in the art and are contemplated herein provided such do not adversely affect the desired properties of the dopes and/or fibers of this invention, e.g., due to factors such as steric hindrance. Generally, it is preferred that no more than two (and more preferably no more than one) suitable substituents be present per aromatic nucleus. However, more than two such substituents may suitably be present if the substituent is a relatively small group e.g., methyl.

Both homo-and co-polyamides having substituted or unsubstituted aromatic nuclei, as described above, are well suited for the dopes and fibers of this invention. Random copolymers are preferred copolymers. By the term "random" is meant that the copolymer consists of molecules containing large numbers of units comprised of two or more different types in irregular sequence. The units may be of AB (e.g., from p-aminobenzoyl chloride hydrochloride), AA (e.g., from p-phenylenediamine or 2,6-dichloro-p-phenylene diamine), or BB (e.g., from terephthaloyl or 4,4'-bibenzoyl chloride) type or mixtures of these, provided always that the requirements of stoichiometry for high polymer formation are met. It is not necessary that the relative numbers of the different types of the unit be the same in different molecules or even in different portions of a single molecule.

One or more of these polymers may suitably be

used in the fibers of this invention, i.e., a single homopolymer; a single copolymer; or homopolymer and/or copolymer blends are suitable herein.

While the polymer chains described above consist essentially of amide links (- CONH -) and aromatic ring nuclei as described above, the polymers useful for preparing the core of this invention may also comprise up to about 10 percent (mole basis) of units not conforming to the above-cited description, e.g., aromatic polyamide-forming units whose chain extending bonds are other than coaxial or parallel and oppositely directed, e.g., they may be metaoriented, or of linkages other than amide, e.g., urea or ester groups.

Among the suitable aromatic polyamides may be named poly(p-benzamide); poly(p-phenylene terephthalamide); poly(2-chloro-p-phenylene terephthalamide); poly(2,6-dichloro-p-phenylene 2,6-naphthalamide); poly(p-phenylene p;p'-biphenyldicarboxamide); poly(p,p'-phenylene benzamide); poly(1,5-naphthylene terephthalamide); ordered aromatic copolyamides such as e.g., copoly(p,p'-diaminobenzanilide terephthalamide), and random copolyamides such as, e.g., copoly(p-benzamide/m-benzamide) (95/5); and many others.

These aromatic polyamides generally have an inherent viscosity and preferably greater than 1.0. Inherent viscosity (ηinh) defined by the following equation:

$$\eta inh = [\ln (\eta rel)/C]$$

wherein (ηrel) represents the relative viscosity and C represents a concentration of 0.5 gram of the polymer in 100 ml of solvent. Exemplary of such aromatic polyamides are those known as the "Kevlar"

series, products of the DuPont corporation, which generally have a straight pull tenacity of about 18 to 25 grams per denier and a knot tenacity of at least about 7 grams per denier. Further examples of such aromatic polyamides and their methods of preparation can be found, for instance, in U.S. Patent Nos. 3,063,966, 3,600,350, 3,671,542 and 3,919,587 all incorporated herein by reference.

Another example of a synthetic polymer suitable for use as the core of the suture of the invention are high strength polyolefins such as polyethylene which provides fibers having a straight pull tenacity of about 25-50 grams/denier and a knot tenacity of about 7 to 17 grams/denier. These polyolefin fibers are characterized by full chain extension and high crystallization and can be prepared: (1) by ultradrawing of the solidified crystalline polyolefin material that is, by further development of the traditional cold drawing process, and (2) by extending the chains in random state (melt or solution) and inducing them to crystallize in the extended form subsequently. Polyolefins having these characteristics and their method of preparation are described in Keller, A. and Barham, P.J. "High Modulus Fibres", Plastics and Rubber International, February, Volume 6, No. 1 (1981), herein incorporated by reference.

The core of the surgical suture of the invention can be either a monofilament or of multifilament construction. The latter is ordinarily preferred since the coating of suture material subsequently applied generally exhibits stronger adhesion to multifilament cores. The liquified suture material coating tends to penetrate and fill the interstices of a multifilament core as well as

coating the core, thereby anchoring the coating thereto. Multifilament cores can take the form of braids, twisted polyfilaments, yarns and the like.* It should be noted that while the synthetic polymer materials contemplated for use as the core of the composite sutures of the invention, have high axial strength, they are not ordinarily suitable for use as sutures since they do not possess the necessary lateral strengtn and, therefore, tend to abrade, kink and/or fibrillate during knotting. Coating of the core with a suture material pursuant to the present invention has been found to unexpectedly stabilize, i.e. provide lateral strength resistance against such action thereby rendering suitable for use as sutures these synthetic polymer fibers normally unsuitable for such use.

The surgical suture material used to coat the core can be any film-forming material commonly used in the construction of absorbable and non-absorbable sutures. In general these suture materials when drawn into fibers exhibit straight tensile strengths of about 4 to 10 grams/denier. Examples of the non-absorbable type suture materials are silk (fibroin), polyolefins, such as polyethylene and polypropylene, polyesters such as polyethylene terephthalate and nylon. Examples of absorbable type materials useful as the coating for

* The suture material in the form of multi or monofilament yarn may also be present initially as a core around which the high strength yarn which eventually becomes the core in the finished suture is braided or twisted or it may be formed into a plied, twisted, braided or co-mingled construction with the high strength yarn.

the core include collagen and the synthetic absorbable materials such as polylactide, polyglycolide and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Patent Nos. 3,636,952 and 2,683,136, which patents are herewith incorporated by reference. Such synthetic absorbable polymers are sometimes referred to herein as simply homopolymers and copolymers of lactide and glycolide.

The amount of suture material coated onto the core will vary depending upon the constructon of the core, whether monofilament or multifilament, the number and tightness of braid or twist, the particular tensile strength and knot tenacity of the core, the particular suture material used as the coating and its nature, e.g. melt, solution or solid. In general, when the coating is a non-absorbable suture material, the coating will constitute about 5 to about 10% by weight of the coated core. On the other hand, when the coating is an absorbable suture material, the coating may constitute about 5 to 90% by weight of the coated core.

The coatings can be applied by a variety of suitable techniques well known in the coating art. For example, the coatings can be applied to the core by solution coating, melt coating, extrusion coating and the like.

In melt coating, for example, the uncoated core under tension is slowly passed through a melt of the suture material and then through a die having an orifice smaller than the upper diameter specification for the suture size desired, heated above the melting point of the coating materials, to trim

off excess coating material and shape the composite. Multiple coatings may be applied if necessary.

In solution coating, the suture material is dissolved in a suitable solvent and the core is slowly passed through the coating solution thus formed. The treated core is then passed continuously through a tubular oven heated to an elevated temperature to evaporate the solvent and coalesce and solidify the suture material that remains.

A preferred coating technique when the core being coated is of multifilament construction comprises initially either solution coating or melt coating the multifilament core while the latter is held under a suitable tension and allowing the liquified coating material to penetrate or infiltrate the interstices of the core, thereby forming roots which help anchor the coating of the core. A second layer of the same suture material may then be applied to the impregnated core by any of the conventional coating methods.

In a typical extrusion coating process the core is passed through the cross-head die of a conventional wire coating extrusion apparatus. Pellets of the coating material are introduced into the plastification zone of the extruder wherein they are plasticized into a melt which is forced through the annular die of the extruder and onto the core.

Which coating technique is employed will usually depend upon the particular core utilized. Aromatic polyamide cores, for example, lend themselves to melt or extrusion coating because of their high melting points. The high strength polyethylene cores, on the other hand, have

relatively low melting points, e.g. about 145°C, and must be treated differently. With them, solution coating of the monoor multi-filament cores is the chief method.

According to a preferred embodiment of the invention, when the core being coated is an aromatic polyamide, it is subjected to both a precoating stage and finish coating stage, each of which will oe discussed below in more detail.

Impregnation/Precoating Stage

The impregnation/precoating operation of the invention can be conducted using a thread composed of a core made up of multifilaments of a suture material and a plurality of fibers of a synthetic polymer having a tenacity of at least 18 grams/-denier and knot tenacity of at least 7 grams/-denier. The thread can be formed in the usual manner as by twisting, braiding, etc., a plurality of the synthetic polymer fibers around the suture material core. The thread, that is, the covered core is then heated to temperatures above the melting point of the multifilament core material passing it through any suitable oven during which passage the suture material melts and under the tension developed and/or applied exudes upward through the polyfilamentous synthetic polymer component and onto its surface. The amount of coating employed should be sufficient to not only fill all the interstices of the multifilament core component during the melting period but to also coat the surface of the yarn or thread component. Any excess coating material which may have melted out is trimmed off. While the heating of the covered core mixed yarns can be effected with or

without stretching of the thread in some instances, a better final suture is obtained when the yarn is maintained under tension with little or no stretch applied at this stage. It is at this stage that the basic solid coated core structure is developed.

The impregnated and coated core is then passed through a heated dye which trims coating nubs from the core and otherwise smooths the external surface of the thread. Stretch may also be applied during the smoothing operation, but again, best results are obtained with no or minimum stretch. The thread may be passed through the heating oven or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface coating be removed, but some of it should be used to fill the ups and down of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the coating remaining on the surface follows the contours of the thread and any subsequently applied coating will follow these contours.

The temperatures employed in the heating oven will vary depending on the coating employed, the proportions of coating material to core, the speed at which the core is passed through the oven and whether the heating and/or smoothing is conducted under stretch conditions. As aforementioned, the temperature should be raised above the melting point to a level at which the coating material exudes through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which thin the coating material to a point where it runs off should be avoided as they tend to exude too

much coating material and fail to produce a solid case structure.

Generally speaking, when the impregnation/precoating operation is conducted under stretch conditions, distribution of the coating material throughout the thread and exudation to the surface occurs at lower temperatures than when no stretch is applied. It is important to note, however, that giving the core a high level of stretch in the impregnation/precoating operation reduces or eliminates the ability to apply stretch in the subsequent finish coating stage, in accordance with the preferred embodiment of the invention described below, where it may be used to adjust finished suture properties such as break elongation by additional heat treatment of the highly stretched precoated thread.

The optimum melting temperatures employed in the impregnation/precoating operation will depend primarily upon which suture coating material is employed. The smoothing die temperature will also be above the melting point of the coating material and below the melting point of the core. Usually it will conform closely to the temperature employed in the impregnation/precoating stage preferably about 5 to 15 degrees below that used in the impregnation/precoating stage.

Finish Coating Stage

In the preferred embodiment of the invention, the final stage in obtaining the composite suture structure is to melt extrude coating material onto the smoothed impregnated/precoated thread. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth precoated

thread is simply fed through the extrusion coating die and coated with additional coating material of the same type as used in the impregnation/ precoating stage. As aforementioned, it is important to note that the smooth impregnated/ precoated thread subjected to the coating stage be essentially free of an undulating surface. The extrusion temperatures employed in the impregnation/ precoating stage although it has been found that the higher the extrusion coating temperature, other conditions being equal, the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperature which results in increased polymer flow under a given applied force.

The following examples are included to further illustrate the novel composite sutures of the invention and their preparation. In the examples, reference is made to the following drawings wherein: Fig. 1 is a schematic drawing of an apparatus useful in the impregnation/precoating stage of the present invention; Fig. 2 is a schematic drawing of an apparatus useful in the extrusion coating of the suture impregnated and precoated by use of the apparatus of Fig. 1; and Fig. 3 is a cross-section of the extrusion die in Fig. 2 on a larger scale.

Example I

Directing attention to the drawings, using a conventional New England Butt braider machine 4 strands of "Kevlar", a tradenamed material of DuPont DeNemours, of 30-50 denier having a straight pull tenacity of approximately 7.5 grams per denier are braided around a single core of continuous 40 denier polypropylene having a straight pull tenac-

ity of approximately 4 grams/denier. The raw braid thus formed is wound around a reel 2, and fed through a tensioner 4, about a feed roll (Godet) 6, guide 8 and into a heated 10 cm long tubular oven. The lumen of an extrusion coating die without feed serve this purpose and is designated Heated Zone I in Fig. 1. A draw roll (Godet) 13 pulls the raw braid through the oven without stretch, that is, at a stretch ratio (SR) of 1:1. The Heated Zone I is maintained at a temperature of 230°C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Heated Zone I, large quantities of excess polypropylene which have melted out are trimmed off manually. The braid then continues through a Guide 15 to Heated Zone II which contains a smoothing die 17 having a 0.2 mm diameter that trims and smooths down nubs that are formed on the braid. Heated Zone II is maintained at a temperature of about 220°C for the smoothing operation. The smoothed braid is pulled through Heated Zone II by a draw roll (Godet) 19 and onto receiving reel 21. The speed at which the braid passes through both Heated Zone I and II is approximately 1-1.8 M/min. The precoated braid is passed through the smoothing die 17 three times so as to obtain an impregnated/precoated braid of the desired smoothness.

Referring to Fig. 2, reel 31 of smooth impregnated/precoated braid prepared as above is passed through a tensioner 33, to feed roll (Godet) 35 which feeds the braid through guide 37 into extrusion coating die apparatus indicated generally

as 39. Polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260°C and the melt is forced by means of extruding weights 43 applied at a force of 0.233 kg to a piston 45 into and through the extrusion coating die.

Directing particular attention to Fig. 3, the extruding coating apparatus is comprised of a holder indicated generally as 47 which houses a hollow lumen member 49 a spinneret 57 having an outlet 52. The lumen member 49 essentially positioned within the holder 47 so as to provide an annular chamber 53. A gasket 55 seals one end of the member 49 within the holder while the other end is supported by slotted plate 60. The lumen member contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the spinneret 57 is positioned a hollow needle 63. The impregnated/precoated thread 65 passes consecutively through lumen member 49, hollow needle 59, outlet 52 and is coated with melt as it emerged from the die. The coating die is maintained at a coating temperature of 235°C.

The coated filament is then taken up on draw roll 48 which applies stretch. Tension is let down on draw roll 50 which is run more slowly than draw roll 48. The yarn velocity is 1.43 M/min. and the total stretch ratio (SR) is 1.02. The finished suture is finally wound around receiving reel 51.

The result is a finished composite suture with a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional area and exhibiting a knot break strength of about 3.2 pounds. A knot break strength of 3.2 pounds is equivalent to USP limits of size 2.0 monofilament suture. Thus,

the composite suture prepared can be used as a 5/0, 4/0, or 3/0 suture.

Example II

The process of Example I is repeated substituting a polyethylene terephthalate core for polypropylene core and extrusion coating in extrusion coating die apparatus 39 with polyethylene terephthalate. The result is a composite suture having a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional volume coated with polyethylene terephthalate exhibiting a knot break strength of about 3.5 pounds which is a knot brek strength above the USP limits for a 2/0 size suture. Therefore, the composite suture prepared could be used for sizes 5/0, 4/0, 3/0 and 2/0 according to the physician's wishes.

Example III

Fibroin (silk) is dissolved in a aqueous solution of 62% zinc chloride to give a solution having fibroin weight % concentrations in the range of 5-20%. The resulting solution is maintained at approximately its boiling point and "Kevlar" yarn of Example I is pulled through the solution at a constant rate as to fully impregnate and coat the yarn. The impregnated and coated yarn is then dried by passing it through a tubular oven maintained at heating temperatures up to 130°C. The heat treatment evaporates the solvent and helps to form a continuous fibroin film. The composite suture is then washed with cold water to remove residual zinc chloride.

The resulting composite suture with a size 5/0 "Kevlar" core containing approximately 5% by weight fibroin exhibits a knot break strength of approximately 3.5 pounds which is equivalent to a silk

suture of size 2.0. In other words, the silk-coated "Kevlar" composite suture could be used instead of silk in the following sizes: 5/0, 4/0, 3/0 and 2/0.

Example IV

A size 5/0 high strength fully chain-extended polyethylene multifilament yarn having a straight pull tenacity of 50 grams/denier and a knot tenacity of 15 grams/denier is pulled through a 10% solution of polyethylene terephthalate in a solvent mixture of methylene chloride containing 31% by weight hexafluoroisopropanol and then passed through a die to trim off excess solution. The coated core is dried in air and the process repeated to build up the coating to a final composite suture containing 10% by weight polyethylene terephthalate. The composite is washed with water and dried again. The resulting composite suture could be used for sizes 5/0, 4/0, 3/0, 2/0 and 1/0.

Example V

Example I is repeated substituting a polyglycolic acid (PGA) core for the polypropylene core and PGA resin for the polypropylene chips. The resulting "Kevlar"/polyglycolic acid composite has a minimum knot break strength in the range of 1550-1700 grams. Since commercial non-absorbable "Prolene" sutures of size 3/0 has a knot strength of 1550-1650 grams, this means that a size 3/0 "Kevlar"/polyglycolic acid suture will retain the knot break strength of 3/0 "Prolene" after absorption of all the polyglycolic acid. Thus, the "Kevlar"/polyglycolic acid suture prepared could be used for sized 3/0, 4/0 and 5/0.

When 6/0 size "Kevlar" reinforcing core is used with a non-reinforcing PGA coating, the core by

itself will give a knot strength midway between size 4/0 and 5/0 based on "Prolene" knot strength but above the USP standards for 4/0. Thus, PGA coated "Kevlar" composites with a 6/0 core could be used for size 6/0, 5/0 and possible size 4/0.

With size 7/0 reinforcing core and PGA non-supportive coating 6/0 strength is obtained. Thus, PGA coated, 7/0 core "Kevlar" can be used for sizes 6/0 and 7/0.

Using high strength, extended chain polyethylene having 50 gram/denier straight breaking tenacity, with approximately 1/3 of this converting to knot tenacity, a 5/0 size reinforcing high strength polyethylene core of about 0.140 mm in diameter will impart at least the knot strength of a 2/0 suture to the composite. Thus, a PGA-coated high strength polyethylene 5/0 core can be used to make sizes 2/0, 3/0, 4/0 and 5/0 absorbable, non-absorbable composite sutures.

With high strength polyethylene 6/0 size reinforcing core of about 0.90 mm diameter and a non-supporting PGA coating, the core itself will provide enough knot strength for sizes 4/0, 5/0 and 6/0 based on the knot strength of "Prolene".

With high strength polyethylene 7/0 size reinforcing core of about .060 - .065 mm in diameter and non-reinforcing PGA coating, the core itself will give knot strength sufficient for 5/0, 6/0 and 7/0 composites based on the knot strengths of "Prolene".

With higher strength materials or by increasing the knot strength of the materials mentioned here, a wider spectrum of sizes could be covered with the same fine sized reinforcing core.

In commercial production, needles may be

attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time witnout a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

Another advantage offered by the composite sutures of the invention is that needles of smaller diameter can be attached thereto. In accordance with this feature of the invention the outside cover or coating of suture material at the end of the composite suture is removed by any suitable means as, for instance, by dissolving the cover using a solvent which solubilizes the cover but not the core. The core at the end of the suture is thereby exposed and onto the core is attached as, for instance, by swagging a needle of smaller outer diamter than would be used with a suture of the same outer diameter. The following example illustrates this feature of applicants' invention:

Example VI

The end of a composite suture prepared according to the general procedure of Example I and having an outer diameter of approximately 0.012 inch is dipped one-eighth inch into boilin xylene until the polypropylene cover softens. The polypropylene cover is then manually scrapped off to expose the 5/0 "Kevlar" core. A 0.014 inch diameter needle is swagged onto the core to provide a suture with a needle having a cross-sectional area reduced approximately two-thirds that of needles required for sutures having a 0.012 inch diameter.

IT IS CLAIMED:

1. A sterile, surgical suture comprising an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams per denier coated with a film and fiber-forming surgical suture material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

2. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is an aromatic polyamide.

3. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

4. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(1,4-benzamide).

5. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

6. A sterile, surgical suture according to claim 1 wherein the surgical suture material is fibroin.

7. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyester.

8. A sterile, surgical suture according to claim 1 wherein the polyester is polyethylene terephthalate.

9. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyolefin having a straight pull tenacity of about

21. A sterile, surgical suture according to claim 2 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided construction.

22. A sterile, surgical suture according to claim 20 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

23. A sterile, surgical suture according to claim 1 wherein the coating of film-forming suture material comprises 5 to 10% by weight of the suture.

24. A sterile, surgical suture according to claim 13 wherein the coating of film-forming suture material comprises 5 to 90% by weight of the suture.

25. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier, with a fiberand film-forming surgical suture material, said coated core when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

26. A method according to claim 25 wherein said coating is effected by solution coating.

27. A method according to claim 25 wherein said coating is effected by melting coating.

28. A method according to claim 25 wherein the coating comprises heating under tension a thread conprised of a plurality of synthetic polymer fibers having a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers

4 to 10 grams/denier.

10. A sterile, surgical suture according to claim 1 wherein the polyolefin is polyethylene.

11. A sterile, surgical suture according to claim 1 wherein the polyolefin is polypropylene.

12. A sterile, surgical suture according to claim 1 wherein the surgical suture material is collagen.

13. A sterile, surgical suture according to claim 1 wherein the surgical suture material is a film-forming absorbable synthetic polymer.

14. A sterile, surgical suture according to claim 13 wherein the absorbable synthetic polymer is selected from the group consisting of film-forming homopolymers and copolymers of lactide and glycolide.

15. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of glycolide.

16. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of lactide.

17. A sterile, surgical suture according to claim 1 wherein the core is in monofilament construction.

18. A sterile, surgical suture according to claim 2 wherein the core is in monofilament construction.

19. A sterile, surgical suture according to claim 18 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

20. A sterile, surgical suture according to claim 1 wherein the core is a plurality of fibers of said snythetic polymer in a twisted yarn or braided constructon.

of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, then smoothing said coating.

29. A method according to claim 28 wherein said smoothing is effected by passing said heated thread through a heated smoothing die.

30. A method according to claim 28 wherein the surgical suture material is selected from polyolefin and polyester.

31. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a straight pull tensile strength of at least 18 grams/denier and a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, smoothing said coating and melt extruding similar surgical suture material onto said smoothed coating.

32. A method according to claim 31 wherein the surgical suture material is selected from polyolefin and polyester.

33. A method according to claim 25 wherein the coating is effected by solution coating.

34. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of synthetic polymer having a knot tenacity of at least 7 grams/denier and a lateral strength insufficient to prevent abrasion, fibrillation or kinking on knotting with a film and fiber-forming surgical material in an amount sufficient to increase the lateral strength of said core and provide resistance against said abrasion, fibrillation or kinking on knotting, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

35. A sterile, surgical suture according to claim 1 having a needle attached to said core.

36. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is an aromatic polyamide.

37. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(p-Phenylene terephthalamide).

38. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(1,4-benzamide).

39. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

1/1

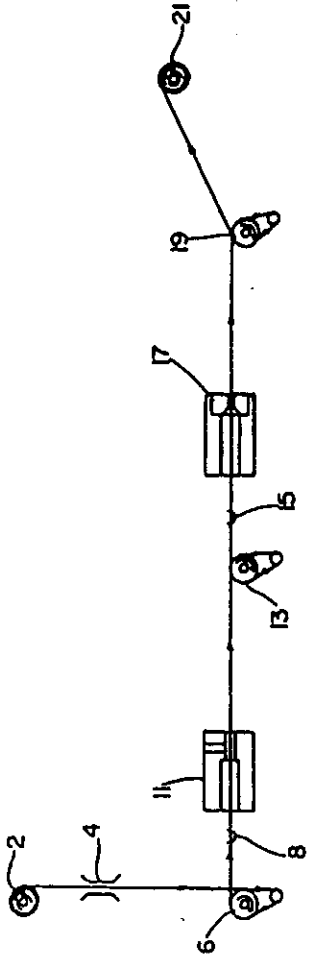


FIG. 1

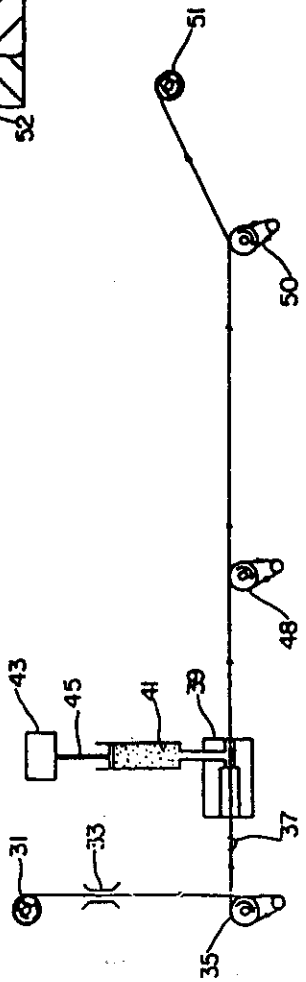


FIG. 2

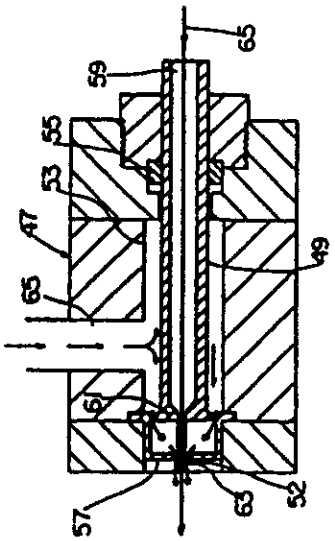


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00918

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int Cl [3] A61L 17/00
US CL 128/335.5

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	128/329R, 334R-335.5, Dig. 8, Dig. 18 28/140, 165, 166, 169 66/169R-170, 202 8/Dig. 21 8/490, 529-533, 115.5-115.7, 130.1-132, Dig. 3,

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

cont'd Dig. 9

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category [15]	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
X, Y	US, A, 3,791,388	12 February 1974 HUNTER	1, 6-9, 11-17, 20, 23-35
Y	US, A, 4,014,973	29 March 1977 THOMPSON	23, 24, 31
Y	US, A, 3,359,983	26 December 1967 NORTHEY	5, 10, 23, 24, 39
Y	US, A, 3,630,205	28 December 1971 LISTNER	5, 10, 23, 24, 39
X, Y	US, A, 4,204,542	27 May 1980 BOKROS	23, 24, 35-38
X, Y	US, A, 4,336,357	22 June 1982 BARTOLI	23, 24, 35-38

* Special categories of cited documents: [19]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [1]	Date of Mailing of this International Search Report [1]
31 JULY 1984	17 AUG 1984
International Searching Authority [1]	**Signature of Authorized Officer [1]**
ISA/US	C. FRED ROSENBAUM

Form PCT/ISA/210 (second sheet) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000180

International Application No PCT/US84/00918

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [2] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [3], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [4]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-24 and 35-39 are drawn to a surgical suture.

Claims 25-34 are drawn to a method of making a surgical suture.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (supplemental sheet (2)) (October 1981)